

**EUROPEAN COMMITTEE ON PHARMACEUTICALS AND PHARMACEUTICAL CARE (CD-P-PH)**

*Set up by the Committee of Ministers under Article 17 of the Statute of the Council of Europe and in accordance with Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.*

**Type of committee:** Steering Committee

Terms of reference valid from: **1 January 2020 until 31 December 2021**

PILLAR/PROGRAMME/SUB-PROGRAMME
<p><b>Pillar:</b> Rule of Law  <b>Programme:</b> Action against crime, safety and security of citizens  <b>Sub-Programme:</b> Quality of Medicines and Healthcare (EDQM, Pharmacopoeia)</p>
MAIN TASKS
<p>Under the authority of the Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia, the CD-P-PH is instructed to:</p> <ul style="list-style-type: none"> <li>(i) fulfil the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), as amended by the Protocol (ETS No. 134), Articles 2, 3, 4 and 8;</li> <li>(ii) fulfil the tasks set out in Resolution CM/Res(2018)1 on the classification of medicines as regards their supply;</li> <li>(iii) minimise public health risks posed by falsification of medical products and similar crimes through: <ul style="list-style-type: none"> <li>a. developing and promoting the implementation of multi-sectorial approaches including co-operation among and within member States, risk management policies, knowledge transfer and prevention models,</li> <li>b. providing support to the Convention on the Counterfeiting<sup>1</sup> of Medical Products and Similar Crimes Involving Threats to Public Health (MEDICRIME Convention) (CETS No. 211), and contributing to the follow-up mechanism ensured by the Committee of the Parties to the above Convention;</li> </ul> </li> <li>(iv) contribute to improving public health and access to good quality medicines and healthcare via developing harmonised provisions and practices for the appropriate use of medicines and promoting the implementation of the pharmaceutical care<sup>2</sup> philosophy and working methods in Europe;</li> <li>(v) ensure and follow up appropriate implementation of the results of the relevant activities of the Council of Europe at national level in States Parties to the Convention on the Elaboration of a European Pharmacopoeia;</li> <li>(vi) facilitate the development and maintenance of links with relevant European institutions and international organisations active in the field, in particular the European Commission and the World Health Organization (WHO);</li> <li>(vii) where deemed necessary, elaborate legal instruments, including resolutions for adoption by the Committee of Ministers, and prepare policies and guidance documents;</li> <li>(viii) hold an exchange of views annually in order to evaluate its activities and advise the Committee of Ministers and the Secretary General on future priorities in its sector including possible new activities and those that might be discontinued;</li> <li>(ix) take due account of a gender perspective in the performance of its tasks;</li> <li>(x) take the pertinent aspects of the European Convention on Human Rights into consideration in its thematic work;</li> <li>(xi) in accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, carry out, at regular intervals, within the limits of the available resources and bearing in mind its priorities, an examination of the convention for which it has been given responsibility,<sup>3</sup> in co-operation, where appropriate, with the relevant convention-based bodies, and report back to the Committee of Ministers;</li> <li>(xii) contribute to the achievement of the UN 2030 Agenda for Sustainable Development, in particular with regards to Goal 3: Good health and well-being.</li> </ul>

<sup>1</sup> The wording "counterfeit" as used in the official title of the Convention should be interpreted as "falsified", without any Intellectual Property Rights (IPR) meaning.

<sup>2</sup> "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (source: Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543).

<sup>3</sup> Cf. relevant decisions of the Committee of Ministers (CM/Del/Dec(2013)1168/10.2) and list of Conventions in document CM(2019)132.

<b>SPECIFIC TASKS</b>
<p>(i) Contribute to patient safety, the accessibility of medicines to patients and the responsible use of medicines through carrying-out the bi-annual revisions of the appendices of Committee of Ministers' Resolution CM/Res(2018)1 on the classification of medicines as regards their supply, promoting the harmonisation of the supply conditions of medicines in member States, and consolidating the co-operation with relevant competent authorities at national and European level active in the field of classification of medicines.</p> <p>(ii) Further contribute to the prevention of and fight against falsified medical products and similar crimes through:</p> <ul style="list-style-type: none"> <li>- developing awareness programmes, events, information materials and publications aimed at fostering political will and cooperation at national and international level;</li> <li>- performing targeted studies in the field of falsified medical products and similar crimes;</li> <li>- providing health and law enforcement officials with a platform, opportunities and tools for information and experience exchange;</li> <li>- while maintaining a multi-sectorial approach, building up and maintaining specific expertise;</li> <li>- supporting the MEDICRIME Convention and its Committee of the Parties.</li> </ul> <p>(iii) Further support the safe and appropriate use of medicines through:</p> <ul style="list-style-type: none"> <li>- the promotion of Committee of Ministers' Resolution aimed at advancing the implementation of pharmaceutical care at national level and encouraging the evaluation of the quality of pharmaceutical care practices (to be adopted in 2019);</li> <li>- the promotion of Committee of Ministers' Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use;</li> <li>- the provision of a forum for exchange of experience on national policies and strategies related to pharmaceutical practices;</li> <li>- the development of guidance documents and standards aimed at optimising the medication use process and encouraging the provision of patient-centred care.</li> </ul> <p>(iv) Review progress towards the United Nations Sustainable Development Goals (UNSDGs), as evidenced by monitoring mechanisms and promoted through standard-setting and exchange of experiences and good practices.</p>
<b>COMPOSITION</b>
<p><b>Members:</b></p> <p>Governments of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia are invited to designate a representative of the highest possible rank with expertise in a field covered by these terms of reference. Each member of the Committee shall have one vote. Where a government designates more than one member, only one of them is entitled to take part in the voting.</p> <p>The sending authorities of the member States will bear the travel and subsistence expenses for their representatives' participation in the meetings of the CD-P-PH. The travel and subsistence expenses of the Chair for participating in the meetings of the CD-P-PH will be borne by the EDQM budget.</p> <p>In accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, in cases where there is no convention-based body including all the Parties, non-member States are invited to take part, with a right to vote, in the committee meetings pertaining to the conventions to which they are Parties.</p> <p><b>Participants:</b></p> <p>The following may send representatives, without the right to vote and at the charge of their corresponding administrative budgets:</p> <ul style="list-style-type: none"> <li>- Parliamentary Assembly of the Council of Europe;</li> <li>- Congress of Local and Regional Authorities of the Council of Europe;</li> <li>- European Court of Human Rights;</li> <li>- Council of Europe Commissioner for Human Rights;</li> <li>- Conference of INGOs of the Council of Europe;</li> <li>- Committees or other bodies of the Council of Europe engaged in related work, as appropriate.</li> </ul> <p>The European Union is entitled to appoint a representative to the meetings of the CD-P-PH, without the right to vote except for the fulfilment of the tasks mentioned under item (i), and without defrayal of expenses.</p> <p>The following may send representatives, without the right to vote and without defrayal of expenses:</p> <ul style="list-style-type: none"> <li>- Council of Europe member States other than those mentioned above under "Members" and other States with observer status to the European Pharmacopoeia Commission;</li> <li>- Observer States to the Council of Europe: Canada, Holy See, Japan, Mexico, United States of America;</li> <li>- World Health Organization (WHO).</li> </ul>

**Observers:**

The following may send representatives, without the right to vote and without defrayal of expenses:

- non-member States with which the Council of Europe has a Neighbourhood Partnership including relevant co-operation activities;
- International professional societies, intergovernmental organisations (IGOs) and non-governmental organisations (NGOs) working on topics related to the tasks of the Committee.

**WORKING METHODS****Plenary meetings:**

38 members, 1 meeting in 2020, 2 days.

38 members, 1 meeting in 2021, 2 days.

Extraordinary meetings of the CD-P-PH can be convened upon request by the Chairperson.

Representatives taking part in the Committee and its subordinate bodies shall complete a declaration of interest and confidentiality undertaking form (EDQM Form/226).

The Committee will also appoint a Gender Equality Rapporteur from amongst its members.

The rules of procedure of the Committee are governed by Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

With a view to reaching its objectives and to enable multidisciplinary working methods, the CD-P-PH may, in derogation of CM/Res(2011)24 and within the limit of budgetary attributions, create subordinate bodies.

Whenever appropriate, it will prioritise environmentally sound working methods, such as virtual meetings facilitated by information technology and written consultations.

**BUDGETARY INFORMATION\***

	Meetings per year	Number of days	Members	Plenary €K	Bureau €K	Working groups	Secretariat (A, B)
2020	1	2	38	8.6	-	-	1 A; 1 B
2021	1	2	38	8.6	-	-	1 A; 1 B

\*The costs include the per diem, travel costs, interpretation, translation and document printing. These costs are calculated on the basis of the 2020 standard costs.